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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,729	06/23/2003	Tom Sprinkle	12873/04605	8729
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			EXAMINER	
			OSTRUP, CLINTON T	
			ART UNIT	PAPER NUMBER
			3771	
			NOTIFICATION DATE	DELIVERY MODE
			02/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com dcunin@calfee.com

	Application No.	Applicant(s)				
Office Action Occurrence	10/601,729	SPRINKLE ET AL.				
Office Action Summary	Examiner	Art Unit				
	CLINTON OSTRUP	3771				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>05 No</u>	ovember 2008.					
	action is non-final.					
<i>;</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1,3-5 and 26-34</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,3-5 and 26-34</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examine	•					
	10)⊠ The drawing(s) filed on <u>05 November 2008</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.					
		•				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
a)						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)	Λ.Π	(DTO 440)				
1) X Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) ∐ Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/SB/08)	atent Application					
Paper No(s)/Mail Date 6) Other:						

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DETAILED ACTION

1. This Office Action is responsive to the amendment filed November 5, 2008. As directed by the amendment, claim s1 and 3 have been amended, claims 2 and 6-25 have been cancelled, and claims 30-34 have been added. Thus, claims1, 3-5 and 26-34 are pending in this application.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4. Claim 30 recites the limitation "said sleeves" and "said posts"; however, there is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 6. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Raje et al (6,823,869).

Regarding claim 1, Raje discloses a mask (10) with a shell (40) and a cushion (30) connected with the shell; the shell having a side wall (Figure A9a 504) and a retaining ring (502) permanently secured (when assembled) to the shell inside the side wall. The side wall and said retaining ring define a gap (500) between the sidewall the retaining ring and the gap extends around the shell. The cushion has a side wall (side of cushion) with an outer peripheral edge portion (edge that contacts the shell) including a tongue (520) extending around said cushion. The tongue of the cushion is received in the gap and being engaged by said retaining ring (when assembled) to secure the cushion to the shell. See: col. 25, lines 29-42 & figures A9a & F44.

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raje et al., (6,823,869) and further in view of Scarberry et al (2002/0100479).

Raje discloses all the limitations of claim 3 except the shell having a plurality of projecting posts and the retaining ring including a plurality of sleeves for receiving the posts to permanently secure the retaining ring inside the side wall of the shell.

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Scarberry teaches a nasal mask (10) with a shell sidewall (side of 12) having an attachment mechanism to enhance the bonding attachment of the seal (18) to the body (12) and specifically describes screws and tacks as attachment means. Since screws and tacks would comprise a plurality of projecting posts, and by using the screws or tacks to adhere the seal to the body, the retaining ring would necessarily have a plurality of sleeves for receiving the screws or tacks (as formed), and the interaction of the posts and sleeves would cause the retaining ring to be supported on the shell. Moreover, Scarberry teaches bosses (42) which are projecting posts for providing additional support to the annular member at the location of the anchorage mechanisms (38). See: page 5 [0047]-[0048] and figures 3-6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modified the means for attaching the seal to the body (shell) via the retaining ring as disclosed by Raje by using screws or tacks to secure seal to the body, as taught by Scarberry, to obtain a mask with a seal that is more securely fastened to the body of the mask.

9. Claims 4-5, 26-29, 31, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palkon et. al. (7,007,696) and further in view of Heidbrink (2,133,699).

Palkon discloses a nasal mask with a shell (16) and a cushion (30) connected with said shell. Palkon discloses a cushion with a side wall (45), an inner wall (46) wherein the inner wall extends transverse to said side wall. The cushion also has an outer wall (48) that tends to transverse the side wall and is adapted to engage and seal

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against the face of a user of the mask (Figs. 1 & 7). Palkon discloses the outer wall of the cushion as extending substantially around the cushion (Figs. 2-5) and Palkon teaches forming a discontinuous region at the nasal bridge area of the cushion (Fig. 2); however, Palkon lacks the specific teaching that the inner wall of the cushion is discontinuous.

Heidbrink teaches a mask with a discontinuous inner membrane at the nasal bridge region that provides a good seal from outside air and adapts to different shapes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the discontinuously shaped nasal bridge portion of the nasal mask disclosed by Palkon, by utilizing the nasal bridge shape taught by Heidbrink, to obtain a nasal mask that provides a good seal to users with differently shaped faces.

Regarding claim 5, Palkon teaches the inner wall (46) as thicker than the outer wall (48) at the lip region, but lacks specifically stating the inner wall as being stronger than the outer wall. See: page 2 [0029]. However, it would be obvious to a skilled artisan that a thicker membrane would be stronger than a thin membrane. See: figure 7.

Regarding claim 26, Palkon discloses an outer wall extending laterally inward from the side wall and the inner wall extending around the side wall.

Regarding claim 27, Palkon discloses a thicker inner wall of a cushion as compared to the outer wall and a thicker wall would be expected to be stiffer than a thinner wall.

Regarding claims 28 and 29, Palkon discloses a thicker inner wall of a cushion as compared to the outer wall and a thicker wall would be expected to be stiffer than a thinner wall and whether the inner wall is spaced from the outer wall when the outer wall seals against the user's face would be dependent upon the force applied to the mask. However, figures 6-11 show an inner wall that is spaced from an outer wall and it could be reasonably expected that they would remain spaced apart in a force dependent manner.

Regarding claim 31, the inner wall (inner wall of 18) of Heidbrink is not present in the nasal bridge region of the cushion.

Regarding claim 32, a gap is formed between the two ends (each side of nasal region of figure 2 of Heidbrink) of the inner wall (inner wall of 18) of the cushion and the nasal bridge region of the cushion. See: figure 2 of Heidbrink.

Regarding claim 34, the combined references teach a nasal mask with a shell (16 of Palkon) and a cushion (30 of Palkon) connected with said shell. Palkon discloses a cushion with a side wall (45 of Palkon), an inner wall (46 of Palkon) wherein the inner wall extends transverse to said side wall. The cushion also has an outer wall (48 of Palkon) that tends to transverse the side wall and is adapted to engage and seal against the face of a user of the mask (Figs. 1 & 7 of Palkon). Palkon discloses the outer wall of the cushion as extending substantially around the cushion (Figs. 2-5 of Palkon) and Heidbrink teaches an inner wall (inner wall of 18) of a cushion having spaced apart ends (each side of nasal region of figure 2 of Heidbrink) that form a gap at the nasal bridge region of the cushion. See: figure 2 of Heidbrink.

10. Claims 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raje et al., (6,823,869) in view of Scarberry et al (2002/0100479) as applied to claims 1 and 3 above, and further in view of Sherwood (5,227,173).

Raje and Scarberry discloses all the limitations of claim 30, except the sleeves being heat staked on the posts to permanently secure the retaining ring to the shell.

Sherwood teaches that the process known as heat staking is a well known technique for securing articles in assembled relation and has found widespread application for joining together plastic molded articles. See: col. 1, lines 9-13.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the post and sleeve interaction disclosed by the combined references, by utilized heat staking, a well known method of securing articles together, as taught by Sherwood, in order to provide a method of securing the posts and sleeves together to form a unitary assembly.

Response to Arguments

- 11. Applicant's arguments filed November 5, 2008 have been fully considered but they are not persuasive.
- 12. Regarding applicant's arguments, to the rejection of claim 1 under 35
 U.S.C. 102(e) as being anticipated by Raje et al (6,823,869), that the retaining ring of
 Raje is not permanently secured to the shell inside a side wall of the shell has not been
 taken well. The mask assembly of Raje, once assembled, has the retaining ring is
 permanently secured to the shell, absent any outside forces. Although the ring may be

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removed, it would be permanently secured to the shell until such forces are applied.

Thus, the rejection of claim 1 has been maintained.

- 13. Regarding applicant's arguments, to the rejection of claim 3 under 103(a) as being unpatentable over Raje et al., (6,823,869) and further in view of Scarberry et al (2002/0100479), that the proposed modification would render the prior art invention being modified unsatisfactory has not been taken well. Simply because there are differences between the two references is insufficient to establish that such references are not combinable. As discussed above and in the previous Office Action, a skilled artisan would be motivated to use the screws or tacks to secure the seal to the body in order to obtain a mask with a seal that is more securely fastened to the body of the mask.
- 14. Regarding applicant's arguments, to the rejection of claims 4-5 and 26-29 under 35 U.S.C. 103(a) as being unpatentable over Palkon et. al. (7,007,696) and further in view of Heidbrink (2,133,699), that the nasal bridge region of Heidbrink is continuous has not been found convincing. Applicant asserts that the inner membrane 19 of Heidbrink is continuous and describe flap 19 as the inner membrane. However, the inner membrane is the interior wall of 18 which is clearly discontinuous about the nasal bridge region of Heidbrink.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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- § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- 17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/ Examiner, Art Unit 3771

/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771